DEPARTMENT OF VETERANS AFFAIRS
CHARTER OF THE
CLINICAL SCIENCE RESEARCH AND DEVELOPMENT SERVICE
COOPERATIVE STUDIES SCIENTIFIC EVALUATION COMMITTEE

1. OFFICIAL DESIGNATION: Department of Veterans Affairs (VA) Clinical Science Research and Development Service Cooperative Studies Scientific Evaluation Committee.

2. AUTHORITY: The Committee is established by directive of the Secretary of VA, and operates under the provisions of the Federal Advisory Committee Act, as amended, 5 U.S.C. App. 2.

3. OBJECTIVES AND SCOPE OF ACTIVITIES: The Committee provides expert advice on VA cooperative studies, multi-site clinical research activities, and policies related to conducting and managing these efforts. Such advice is to ensure that new and ongoing activities are based on scientific merit, mission relevance, and quality, and are conducted efficiently, safely, and economically. To accomplish these objectives, the Committee reviews proposals and makes recommendations to the Director of the Clinical Science Research and Development Service and Chief Research and Development Officer on their funding and administration. The Committee does not consider grants, contracts, or other forms of extramural research for VA.

4. DESCRIPTION OF DUTIES: The Committee reviews proposed and ongoing cooperative studies and multi-site clinical research activities (including clinical trials, epidemiological studies, and related efforts) and advises VA on scientific merit, feasibility, the adequacy of the plan of investigation, related activities and requested resources, technical details including the involvement of human subjects, and mission relevance. The Committee evaluates and discusses written materials supplied by the proponents of each project as part of its review process, and may hold face-to-face discussions with proponents to further obtain additional information about proposals. Thereafter, the Committee deliberates on the projects and communicates its recommendations to the Director of the Clinical Science Research and Development Service.

5. OFFICIAL TO WHOM THE COMMITTEE REPORTS: The Committee reports to the Director of the Clinical Science Research and Development Service.

6. OFFICE RESPONSIBLE FOR PROVIDING THE NECESSARY SUPPORT FOR THE COMMITTEE: Support for the Committee is provided by the Office of Research and Development, Veterans Health Administration, Department of Veterans Affairs.

7. ESTIMATED ANNUAL OPERATING COSTS IN DOLLARS AND STAFF YEARS: The estimated annual cost for operating the Committee is $150,000 and about 1.5 staff years. All members will receive travel expenses and a per diem allowance in

accordance with the Federal Travel Regulation for any travel made in connection with their duties as members of the Committee.

8. DESIGNATED FEDERAL OFFICER: The Designated Federal Officer (DFO), a full time VA employee, will approve the schedule of Committee meetings. The DFO or a designee will be present at all meetings, and each meeting will be conducted in accordance with an agenda approved by the DFO. The DFO is authorized to adjourn any meeting when he or she determines it is in the public interest to do so.

9. ESTIMATED NUMBER AND FREQUENCY OF COMMITTEE MEETINGS: The full Committee meets up to three times annually.

10. DURATION: The Committee performs a continuing service, unrestricted as to time, except as periodic review of its functions shall indicate that it is no longer needed. The Committee's continued operation is contingent upon renewal of this charter by appropriate action prior to its expiration.

11. COMMITTEE TERMINATION DATE: Unless renewed by appropriate action prior to its expiration, the Committee will terminate 2 years from the date below.

12. MEMBERSHIP AND DESIGNATION: The Committee is composed of members having experience and expertise in major medical specialties and disciplines, including biostatistics and epidemiology, and selected based on professional expertise and achievement in clinical research. Committee membership shall represent, to the extent possible, diversity in race/ethnicity, gender, and geographical background. Members will serve 4-year staggered appointments.

The Committee will be composed of approximately 12 members. Several members may be Regular Government Employees, but the majority of the Committee's membership will be Special Government Employees. Committee members will serve as objective advisors, not as representatives of any organizations for which they may otherwise be serving.

13. SUBCOMMITTEES: The Committee is authorized to establish subcommittees, with the DFO's approval, to perform specific projects or assignments as necessary and consistent with its mission. The Committee chair shall notify the Director of the Clinical Science Research and Development Service, through the DFO, of the establishment of any subcommittees, including its function, membership, and estimated duration. Subcommittees will report back to the Committee. A member of one subcommittee may serve as a member of other subcommittees when his or her expertise is required.

14. RECORDKEEPING: Records of the Committee shall be handled in accordance with General Records Schedule 26 or other approved agency records disposition schedules. Those records shall be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. § 552.

15. DATE CHARTER IS FILED:

Approved: John R. Gingrich Date: 7/12/12

John R. Gingrich
Chief of Staff